

### **REMARKS/ARGUMENTS**

By the present amendment, claims 42, 53, 60 and 61 have been amended in order to replace the phrase "a sufficient portion" with "at least the N-terminal domain and hydrophobic domain". This amendment finds support in the application as filed, for example on page 22, line 23 to page 23, line 2. Claims 58 and 59 have also been amended in order to remove the term "gene" consistent with the previous amendment made to claim 42. Withdrawn claims 68 and 69 have been cancelled.

The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. No new matter has been entered by the present amendment and its entry is respectfully requested.

The office action dated July 1, 2008 has been carefully considered. It is believed that the amended claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

#### **Restriction Requirement**

In response to the Restriction Requirement dated June 12, 2007, Applicant elected to proceed with the claims of Group I comprising claims 42-67. By the present amendment, the claims of Groups II and III have been cancelled. In the June 12, 2007 office action, the Examiner further requested that Applicant elect several species in Group I. Applicant elected certain species which are not contained in current claims 51-55 and 62. As a result, the Examiner is considering these claims as withdrawn. However, at present, there is no prior art of record against the generic claims. Therefore, under 37 CFR 1.141, Applicant is entitled to consideration of claims to additional species which depend from, or require, all of the limitations of an allowable

claim. Therefore, we respectfully request that once the independent claims are considered in order for allowance, the Examiner rejoins the dependent claims 51-55 and 62 to the non-elected species. Accordingly, claims 51-55 and 62 are being maintained in the application.

**35 USC §112, Second Paragraph**

The Examiner has objected to claims 42, 60 and 61 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner has rejected these claims in light of the phrase "sufficient portion" which the Examiner alleges is not clear. While not agreeing with the Examiner, Applicant has amended the claims in order to delete reference to "sufficient portion" and to specify that the oil body protein comprises at least the N-terminal domain and hydrophobic domain. Accordingly, the claims are clear in specifying what portions of the oil body protein are required for targeting.

In view of the foregoing, we respectfully request that the objection to the claims under 35 USC §112, second paragraph, be withdrawn.

**35 USC §112, First Paragraph**

**(a) Enablement**

The Examiner has objected to claims 42-50, 56-61 and 63-67 under 35 USC §112, first paragraph, alleging that the specification does not reasonably provide enablement for any chimeric nucleic acid sequence encoding a fusion protein comprising any nucleic acid sequence that encodes "a sufficient portion" of an oil body protein or any oleosin of undefined structure.

In response, Applicant has amended the independent claims in order to specify that the oil body protein comprises at least the N-terminal domain and hydrophobic domain of an oil body protein. Oil body proteins, such as oleosins and caleosins, were well known in the art at the time of filing the present application. In particular, as described in the

application, oleosins were isolated and sequenced from numerous species including, without limitation, *Arabidopsis thaliana*, corn, rapeseed, carrot, sunflower, soybean and cotton (see page 4, line 18 to page 5, line 10). Oil body proteins, including both oleosins and caleosins, from different species share structural similarity in that they all comprise three domains, an N-terminal domain, a central hydrophobic domain and a C-terminal domain. Further, the Examiner acknowledges that the structure of oleosins is conserved in the following statement:

"there are more than 40 different oleosins, comprising a characteristic central hydrophobic domain of ~70-75 uninterrupted and uncharged residues that forms an hairpin loop around three conserved proline residues around which flanked by relatively polar C-terminal (~65 residues) and N-terminal domains (~50 residues)  
... "

Therefore, one of ordinary skill in the art could readily make and use the claimed invention based on the guidance provided in the application and the level of skill and common general knowledge in the art. In particular, one of skill in the art could readily prepare a nucleic acid sequence encoding at least the N-terminal domain and hydrophobic domain of an oil body protein without undue experimentation. These domains are readily identifiable and can be easily obtained for use in the claimed method.

In view of the foregoing, we respectfully request that the objections to the claims as lacking enablement be withdrawn.

**(b) Written Description**

The Examiner has objected to claims 42-50, 56-61 and 63-67 under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states that claims 42-50, 56-60 and 63-67 are directed to any chimeric nucleic acid sequence encoding a fusion polypeptide comprising any nucleic acid sequence that encodes a "sufficient portion" of an oil body protein or any oleosin of undefined structure. As noted above, the claims have now been amended in order to specify that the oil body protein comprises the N-terminal domain and the hydrophobic domain of the oil body protein. Applicant clearly had possession of such an oil body protein in the application as filed. In particular, as noted previously, the structure of numerous oil body proteins were known in the art at the time the application was filed. In addition, oil body proteins from different species share structural similarity in that they all comprise three domains, an N-terminal domain, a central hydrophobic domain and a C-terminal domain. Applicant also specifically provides the amino acid sequence of two oleosin proteins from *Arabidopsis thaliana* and *Brassica napus*, as well as one caleosin sequence from *Arabidopsis thaliana*. Further, Applicant provided working examples showing that the two oleosins and one caleosin work in the claimed method. Specific examples of 3 species coupled with the knowledge in the art of the sequences of other oil body proteins is sufficient to provide written description for the claimed genus. As noted in the office action:

"the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus." (emphasis ours)

Applicant has demonstrated reduction to practice of 3 oil body proteins and has also disclosed relevant, identifying characteristics of the claimed oil body proteins in that they must comprise the N-terminal and hydrophobic domain.

It appears that the Examiner is applying the written description guidelines for the method claims as if the claims were directed to nucleic acid sequences *per se*. In particular, the Examiner is suggesting that the claims are limited to specific exemplified sequences, as Applicant has not provided the sequence of every species within the genes. As noted above, the members of the genus share common structural features which is sufficient to satisfy the written description requirement. Further, with respect to method claims, where the novelty is in the method, reference to a particular nucleic acid sequence is not required. In this regard, we refer to Example 18 of the training materials for the Written Description Guidelines. Example 18 relates to a method for producing proteins using mitochondria from *Neurospora crassa*. There was only one example provided but the claim was held to satisfy the written description requirements without reference to a sequence.

Accordingly, Applicant had possession of an oil body protein comprising at least the N-terminal domain and hydrophobic domain of an oil body protein at the time the application was filed.

In view of the foregoing, we respectfully request that the objections to the claims under 35 §112, first paragraph as lacking written description, be withdrawn.

The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater

detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1682 at his convenience.

Respectfully submitted,

**MAURICE M. MOLONEY**

By 

Micheline Gravelle  
Reg. No. 40,261

Bereskin & Parr  
Box 401, 40 King Street West  
Toronto, Ontario  
Canada M5H 3Y2

Tel: 416-957-1682  
Fax: 416-361-1398